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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,110

Applicant(s)

BOREN ET AL.

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5-20-03 (response to restriction).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

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Applicant's election with traverse of 05-20-02 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the two Groups have a corresponding special technical feature because both are concerned with treating *H. pylori* infection. This is not found persuasive. Treatment of *H. pylori* infection cannot be a special technical feature because it does not represent a contribution over the prior art. See, for example, page 5 lines 4-13 of Zopf et al. (3). The Examiner has explained in the previous Office action why the fucosylated N-acetyl lactosamine carbohydrate structure is not a corresponding technical feature, and Applicant has not presented any counterargument. The requirement is still deemed proper and is therefore made FINAL.

An action on the merits of claims 15-24 follows. Claims 25 and 26 are withdrawn as non-elected.

Claim 15 is objected to as informal because in line 2, "patent" should be --patient--.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

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subject matter which the applicant regards as his invention.

Claims 17, 18, 20, 21, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 17 depends from itself. Therefore, claim 17 and its dependents are indefinite because the metes and bounds cannot be determined. Applicant is advised that with respect to the prior art, claim 17 has been treated herein as if it depended from claim 16.

Claim 18 is indefinite because the phrase "substantially reduces" has no particular art-recognized meaning and has not been adequately defined in the specification. Thus the metes and bounds of claim 18 and its dependents cannot be determined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by EKLIND et al. (1). EKLIND teaches that several fucosylated N-acetyl lasctosamine carbohydrate structures may be used to treat diseases in humans caused by *H. pylori* infection of human gastric mucosa. See reference claims 13 and 14. Thus claim 15 is anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHMIDT *et al.* (A1).

Applicant claims a method of treating diseases in humans caused by *H. pylori* infection of human gastric mucosa by administering a fucosylated N-acetyl lactosamine carbohydrate structure.

SCHMIDT teaches glycomimetics of sialyl Lewis x and sialyl Lewis a which may be used to treat *Helicobacter pylori* infection; see column 16, lines 28-31. SCHMIDT states at column 2 lines 3-8, "Due to the structural complexity of SLeX and SLeA, the use of simpler, structurally modified mimetics as antagonists for modulating or suppressing excessive leukocyte adhesion is a promising therapeutic starting point for a strategy for alleviating or healing the above-mentioned disorders." SCHMIDT also discloses in the first full paragraph in column 2 that sialyl Lewis x has been administered to patients. SCHMIDT does not explicitly disclose administration of sialyl Lewis x or sialyl Lewis a for treatment of *Helicobacter pylori* infection.

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It would have been obvious for a person of ordinary skill in the art at the time of the invention to administer sialyl Lewis x or sialyl Lewis a for treatment of *Helicobacter pylori* infection as claimed. A worker of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, because sialyl Lewis x or sialyl Lewis a represent substructures of the naturally occurring selectin ligands (see the sentence bridging columns 1 and 2 of SCHMIDT), and thus would have been expected to be effective in controlling the cellular adhesion process underlying the *H. pylori* infection. Likewise, dimers or multimers of these of these moieties would possess the required structural features for binding, and thus be expected to be effective.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

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INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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